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**TO:** Commissioner Paul J. Cote, Jr. and Members of the Public Health Council

**THROUGH:** Paul Dreyer, Ph.D., Associate Commissioner, Center for Quality Assurance and Control

**FROM:** Grant Carrow, Ph.D., Deputy Director, Center for Quality Assurance and Control

**DATE:** January 24, 2006

**RE:** Informational Briefing on Amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C

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**Introduction**

The Drug Control Program proposes to amend regulations to enhance the Massachusetts Prescription Monitoring Program (PMP). The PMP is a critical tool for addressing the problems of illicit use and abuse of prescription drugs in the Commonwealth. The purposes of the enhancements are to improve data quality, increase data utility and utilization, reduce the opportunities for drug diversion and increase prevention of and facilitate interventions in drug addiction and abuse. Specifically, the amendments would:

1. Require pharmacies to obtain positive customer identification before dispensing Schedule II drugs;
2. Require pharmacies to report to the Department additional information about Schedule II prescriptions; and
3. Authorize the Department to share information about potential diversion of Schedule II controlled substances with practitioners and pharmacies.

These amendments would enable implementation of a number of the recommendations in the Commonwealth's *Substance Abuse Strategic Plan* and are one of a number of steps the Drug Control Program is taking to enhance the PMP as part of enhancement initiatives funded in part by the U.S. Department of Justice. While the amendments proposed here are not intended to address every possible area of regulatory enhancement of the PMP, they are a first and necessary step toward enabling the Program to reach its full potential to protect the public health and safety.

**Background**

Prescription drug abuse is a critical public health problem for Massachusetts and the nation. The 2004 National Survey on Drug Use and Health indicated that the category of drug use with the

highest number of new initiates was non-medical use of pain relievers, totaling 2.4 million new users. In Massachusetts, emergency department visits for non-heroin related opioid use, which includes prescription drugs such as OxyContin and other oxycodone products, increased 134% between 1999 and 2002. Treatment data from the U.S. Substance Abuse and Mental Health Services Administration shows that treatment admissions in Massachusetts for the category "other opiates", which includes prescription opioid analgesics, increased 950% in the decade from 1992 (325 admissions) to 2002 (3,089 admissions). Over a similar period, from 1993 to 2003, the Massachusetts PMP showed that the number of prescriptions for all Schedule II opioids, including oxycodone products, increased 150% from 700,000 to 1.74 million. At the end of that period, in 2003, the U.S. Drug Enforcement Administration reported that Massachusetts ranked 11$^{th}$ among the states in the per capita rate of consumption of oxycodone products.

The Department established the PMP in 1992, pursuant to joint regulations with the Board of Registration in Pharmacy, to help address the problem of drug diversion and abuse in the Commonwealth. The program utilizes a computer-based, Electronic Data Transfer (EDT) system to collect prescribing and dispensing information on Schedule II drugs, which are those pharmaceuticals with the highest potential for abuse and are, consequently, among those most sought for illicit and inappropriate use. During FY05, approximately 1,200 community, clinic and hospital outpatient pharmacies in Massachusetts collectively reported over 2.6 million prescriptions for Schedule II drugs to the EDT system.

Data from the system is used to determine prescribing and dispensing trends; provide educational information to health care providers; and provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion. Medical Review Groups (MRGs), comprised of practitioners and pharmacists, provide peer review of the medical data and assist the Department in reviewing data for release to law enforcement and regulatory agencies. Since 1994, data related to over 1700 cases have been reviewed by the MRGs, largely in response to requests from such agencies for information related to ongoing investigations.

The Department also has the authority to release PMP data to practitioners. M.G.L. c. 94C, §24 authorizes the Department to notify practitioners when a patient receives a controlled substance from more than one source and in quantities harmful to the health of the patient. Section 24 also authorizes the Department to adopt regulations to prevent the dispensing of a controlled substance to the same individual from multiple sources or the unlawful diversion of controlled substances. To date, the Department has not promulgated regulations to carry out this section of the law.

Department staff believe that the current system can be improved with respect to customer identification. Currently, the regulations require the pharmacist to "make a good faith effort" to verify the ID of the person picking up a prescription for a Schedule II drug. As a consequence of this language, some individuals seeking to divert prescription drugs are able to obtain Schedule II drugs without showing an ID. Even after enforcement efforts with pharmacies, 25% of prescription records in the database lack customer IDs. Since the customer ID is the only information currently reported on prescription recipients, even for those records with an ID, the Department does not hold all of the information that might be useful in identifying persons engaged in unlawful diversion.

The current 'good faith effort' requirement limits the effectiveness of the PMP. The Department is unable to identify unique individuals in the database with an acceptable degree of confidence. This, in turn, reduces the ability of the Department to release useful data to practitioners and to effectively analyze the data to determine the incidence, prevalence and patterns of Schedule II drug use and abuse in Massachusetts. The amendments proposed here are designed to address these issues.

## Approach

We propose to require that positive identification be obtained by pharmacies from the person picking up a Schedule II prescription. This requirement would help deter diversion of Schedule II drugs by ensuring that pharmacists consistently obtain information about customers obtaining such controlled substances on behalf of patients. Moreover, the requirement would ensure that the reports received by the PMP from pharmacies about the filling of Schedule II prescriptions contain more reliable information. The amendments would provide for exceptions to the requirement for positive identification to ensure that patients will not be unreasonably denied access to needed medications.

We further propose to require reporting by pharmacies of additional prescription information, including patient identifying information such as name and address. The fields proposed to be reported will improve the Department's ability to identify unique individuals in the database. The fields are those recommended by the Alliance of States with Prescription Monitoring Programs and the National Association of State Controlled Substances Authorities and are required to be reported to PMPs in many other states. Adding these fields would facilitate sharing of data with practitioners about prescriptions for Schedule II drugs and would enable statistically valid epidemiological analysis of prescription drug use and abuse. The patient information would be entirely confidential and could be disclosed only as provided in the regulations.

We also propose to authorize the sharing of PMP data with practitioners and pharmacies when patients seek prescriptions from more than one practitioner. By making data available to medical practitioners, the PMP could assist in identifying those at risk for or involved in prescription drug abuse and diversion, who then can be referred to appropriate treatment and/or interdiction. This initiative would assist practitioners concerned about drug diversion and provide a tool for improving care for their patients, including identification and prevention of drug abuse.

These proposed amendments would set forth the requirements for clinic and hospital outpatient pharmacies. The Board of Registration in Pharmacy would need to promulgate companion amendments to set forth the same requirements for community pharmacies.

## Conclusion

Enhancement of the Massachusetts PMP is a prominent goal of the Commonwealth's *Substance Abuse Strategic Plan*. In addition, DPH has been awarded grants from the U.S. Department of Justice to design and implement technological and other enhancements to the Program. Department staff believe that the regulatory amendments proposed here are critical to the success of these initiatives and to the ultimate goal of providing better data on use and misuse of Schedule II opioids and other drugs. The amendments would better enable DPH to assist law enforcement and regulatory agencies in intervention with prescription fraud and other forms of drug diversion and to assist health care providers in detection and identification of individuals at risk for or involved in non-medical use of Schedule II pharmaceuticals.

## Public Hearing

This is to notify the Public Health Council that the Drug Control Program plans to hold a public hearing on these proposed changes to 105 CMR 700.000 in February.

105 CMR 700.000: IMPLEMENTATION OF M.G.L. c. 94C

105 CMR 700.001: Definitions

Customer identifier means the identification number on a valid government issued identification, as specified by the Department, which a pharmacy obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed.

700.006: Requirements for Records, Inventories, and Reports

(J) Prescription Monitoring Program.
  (1) Pharmacy Reporting Requirements.
    (a) Every pharmacy located in a health facility registered with the Commissioner that dispenses controlled substances in Schedule II pursuant to a prescription, shall, in accordance with standards established by the Department, transmit to the Department or its agent the following information for each such prescription:
      (i) pharmacy number (NCPDP);
      (ii) pharmacy prescription number;
      (iii) customer identifier, as defined in 105 CMR 700.001;
      (iv) patient name;
      (v) patient address;
      (vi) patient date of birth;
      (vii) patient gender;
      (viii) relationship of customer to patient;
      (ix) national drug code (NDC) of controlled substance dispensed;
      (x) date prescription written by prescriber;
      (xi) date the controlled substance is dispensed;
      (xii) metric quantity of controlled substance dispensed;
      (xiii) estimated days supply of controlled substance dispensed;
      (xiv) prescriber's U.S. Drug Enforcement Administration (DEA) registration number; and
      (xv) prescription coverage type.
    (b) 105 CMR 700.006(J) shall not apply to medication orders in hospitals.
    (c) A pharmacy that dispenses a Schedule II controlled substance in accordance with 105 CMR 701.004, but is unable to obtain and report the customer identifier required by 105 CMR 701.004, shall leave the customer identifier field blank.
    (d) The information required by 105 CMR 700.006(J) shall be transmitted to the Department or its agent, in accordance with any procedures established by the Department, no later than 15 days following the last day of the month in which the prescription was dispensed by use of:
      (i) electronic device, including but not limited to computer diskette, compact disk, magnetic tape, or modem transmission in a format approved by the Department, or other acceptable electronic method approved by the Department; or
      (ii) Universal Claim Form or other form approved by the Department.
    (e) Pharmacies reporting data from 25 or more prescriptions in any given month must provide the required information in accordance with 105 CMR 700.006(J)(1)(d)(i).

(2) Prescription Monitoring Program Advisory Board.

(a) The Commissioner of the Department of Public Health shall establish a Prescription Monitoring Program Advisory Board to assist in the implementation of 105 CMR 700.006(J) and any other related regulations. The membership of this Advisory Board shall include representatives of the Department of Public Health; Executive Office of Public Safety; disciplinary authorities, including the Boards of Registration in Medicine, Pharmacy, Dentistry, Podiatry, Veterinary Medicine, Nursing and Physician Assistants; representatives of associations or societies representing professions authorized to issue or dispense prescriptions, patient interests, and privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(b) The Prescription Monitoring Program Advisory Board shall assist the Department in designing education programs for the proper use of Schedule II drugs.

(3) Prescription Monitoring Program Medical Review Group.

(a) The Commissioner shall establish Prescription Monitoring Program Medical Review Groups, to recommend accepted medical practice standards for the implementation of 105 CMR 700.006(J) and related regulations. The membership of each Medical Review Group shall consist of two or more registered practitioners, one of whom shall be affiliated with a health care facility, and at least one registered pharmacist. In all cases, members of the Medical Review Groups shall be registered health care practitioners and a majority shall be registered in the same discipline as the practitioner whose records are under review. Registered practitioners shall be designated by the Commissioner from lists approved by the appropriate Boards of Registration in the discipline under which records will be reviewed. Such lists shall be provided by the respective statewide professional societies, whose membership shall fully represent the complete geographic and practice differences represented in the state as a whole.

(i) In the event that insufficient listings are available to comprise the appropriate membership of any particular Medical Review Group, the Commissioner may appoint additional members.

(ii) Whenever possible, the practitioners on a particular Medical Review Group shall be specialists, as designated by a national accrediting board acceptable to the Commissioner, in the same field as the practitioner whose records are being reviewed.

(iii) In all cases, practitioners serving on the Medical Review Group must have a valid Controlled Substance Registration for prescribing Schedule II drugs, pursuant to M.G.L. c. 94C, § 18.

(b) The Medical Review Group shall assist the Department in the evaluation of prescription information.

(4) Privacy and Confidentiality.

(a) Except where otherwise provided by law or judicial order, the information collected pursuant to 105 CMR 700.000 shall not be disseminated by the Department to anyone other than:

(i) a duly authorized representative of the board or agency responsible for registration, regulation or discipline of practitioners authorized to prescribe or dispense Schedule II controlled substances acting in accordance with official duties;

(ii) a law enforcement agency when acting in accordance with its official duties in conducting a bona fide criminal investigation or prosecution of criminal violations. Requests for inspection of these records shall first be directed to the Office of the Attorney General of Massachusetts, or to the Massachusetts State Police Diversion Investigation Unit, or the

United States Drug Enforcement Administration, for notification and approval prior to action by the Department;

(iii) a practitioner, including a pharmacy, in accordance with 105 CMR 700.006(J)(4)(d); or an individual who is the data subject that has access to this data pursuant to a statute or regulation of the Commonwealth.

(b) All requests for information pursuant to 105 CMR 700.006(J)(4)(a)(i) and (ii) shall be in writing. All such information generated shall be reviewed and approved by the Commissioner or a designee and the Medical Review Group prior to release by the Department.

(c) In the event that the Department, through computer analysis and review of the records generated by the prescription monitoring program, finds patterns of prescribing or dispensing that raise questions regarding patient health care or safety or drug diversion by patients, pharmacists or practitioners, the Department shall provide such information to the appropriate Medical Review Group for review and possible referral, as provided for in 105 CMR 700.006(J)(4)(a)(i) and (ii).

(d) Notwithstanding the provisions of 105 CMR 700.006(J)(4)(c), in the event that the Department has reason to believe that a person has obtained or is seeking to obtain prescriptions for a Schedule II controlled substance from more than one practitioner in violation of chapter 94C or 105 CMR 700.000, the Department may provide practitioners who have dispensed such controlled substances or are evaluating the need for dispensing such controlled substances with information concerning prior dispensing to the person of such controlled substances.

## 105 CMR 701.000: REGULATIONS ADOPTED JOINTLY BY THE DEPARTMENT OF PUBLIC HEALTH AND THE BOARD OF REGISTRATION IN PHARMACY FOR THE IMPLEMENTATION OF M.G.L. c. 94C

### 105 CMR 701.004: Requirements for Positive Identification for Dispensing of a Controlled Substance in Schedule II.

(A) A pharmacy shall require that a customer identifier, as defined in 105 CMR 700.001, be presented by the ultimate user or agent of the ultimate user to whom a prescription for a controlled substance in Schedule II is dispensed.

(B) The requirement in 105 CMR 701.004(A) may be waived provided that:

(1) the pharmacy has reason to believe that the failure to dispense the controlled substance would result in a serious hardship for the ultimate user or agent of the ultimate user, and documents the reason; and

(2) the ultimate user or agent of the ultimate user prints his or her name and address on the reverse side of the prescription and signs his or her name thereto.